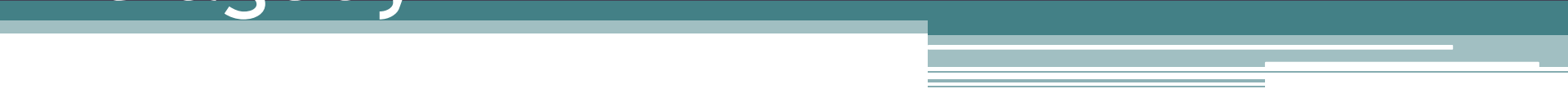


# History, Scandals and Tragedies: Beecher, Tuskegee, Willowbrook and the Rest

Susan E. Lederer, Ph.D.  
University of Wisconsin  
School of Medicine and  
Public Health

A series of horizontal lines in teal and white, located on the right side of the slide, extending from the top of the white section down towards the bottom.

# U.S. legislation as response to tragedy

A series of horizontal lines in teal, light blue, and white, extending from the left edge of the slide and ending on the right side, positioned below the title.

# Collier's

THE NATIONAL WEEKLY



BERTHE LABOVITZ

Political cartoonist and publisher of the "New York Journal". He was one of the most prominent cartoonists of the time. He was also a writer and a publisher. He was one of the most prominent cartoonists of the time. He was also a writer and a publisher.

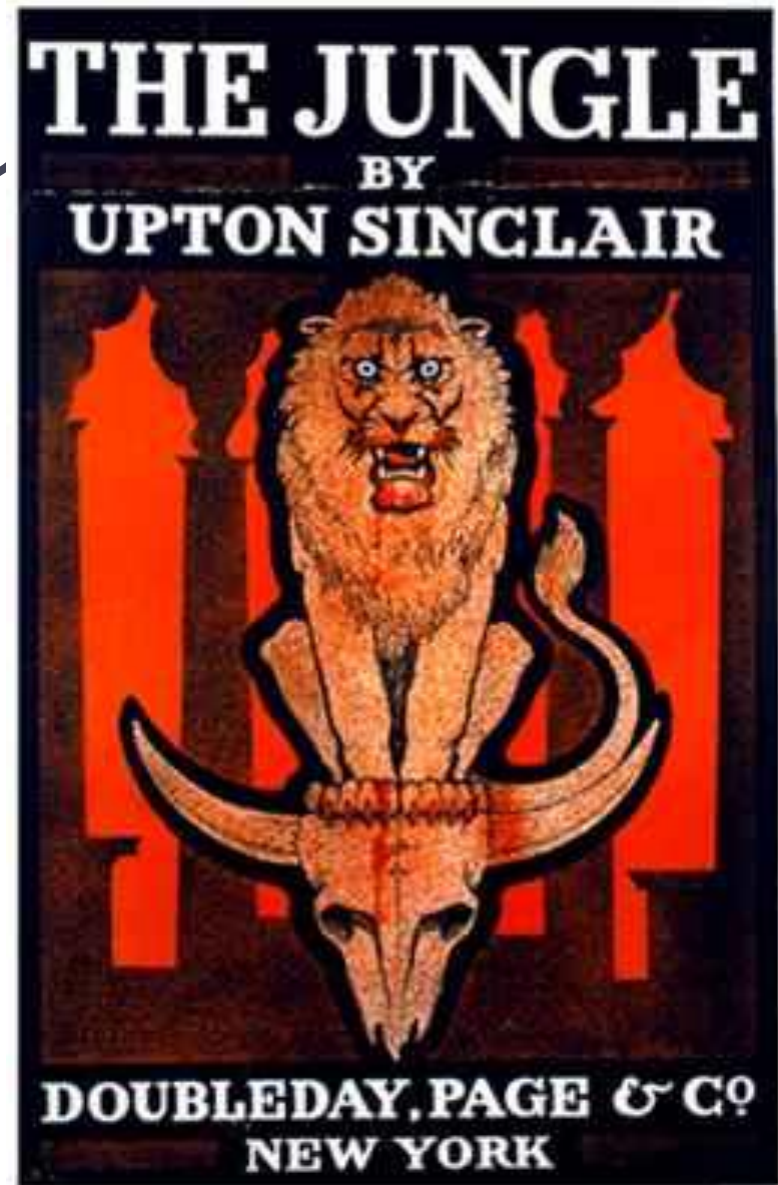
ANOTHER OF COLLIER'S DISGUSTING CARTOONS OF 1906



**COCAINE**  
**TOOTHACHE DROPS**  
Instantaneous Cure!  
**PRICE 15 CENTS.**  
Prepared by the  
**LLOYD MANUFACTURING CO.**  
219 HUDSON AVE., ALBANY, N. Y.  
For sale by all Druggists.  
(Registered March 1885.) See other side.



# Food and Drug Act



# Elixir of Sulfanilamide tragedy

107 deaths

AT YOUR END OF THE  
COAL CHEMICAL PIPELINE . . .



**NEW**  
*Magic Bullets*  
for  
**Murdering Microbes**

Coal chemicals are the steadfast allies of the medical sciences in his uphill conquest of disease. Pyridine, for example, is vital in the manufacture of mella drugs. And gamma-picoline, another valuable Pittsburgh coal chemical, is the source of isonicotinic acid hydrazide, the drug which has shown bright promise in the experimental treatment of tuberculosis in recent months.

Because we control every step in the production of these coal chemicals—from coal to finished chemicals—we're able to provide the medical and pharmaceutical fields with products of exceptional high quality and purity. This same assurance of quality extends through the closely integrated production of our entire Neville Island plant.

Whether you need coal chemicals, agricultural chemicals, dyestuffs, or the products of any of our other divisions, you'll find Pittsburgh Coke & Chemical a reliable source . . . because we're here.

Alkyl methyl pyridinium chloride  
Benzene meta, para-Cresol ortho-Cresol  
Naphthalene Phenol Phthalic Anhydride  
alpha-Picoline beta, gamma-Picoline  
Isonicotinic Acid  
Pyridine Sodium Cyanide  
Toluene Xylene Xylol

**PITTSBURGH COKE & CHEMICAL CO.**  
Grant Building - Pittsburgh 16, Pa.

COAL CHEMICALS • AGRICULTURAL CHEMICALS • DYE CHEMICALS • PROTECTIVE COATINGS • PLASTICISERS • ACTIVATED CARBON • COKE • GASOLINE • HIGH PITCH

Click the "X" in the upper right hand corner of this window to return

ONE GALLON ELIXIR ONE GALLON

**SULFANILAMIDE**

Each fluidounce represents:  
Sulfanilamide, 40 grs.

**SUGGESTED FOR THE TREATMENT OF ALL CONDITIONS  
IN WHICH THE HEMOLYTIC STREPTOCOCCI APPEAR**

Dose, begin with 2 to 3 teaspoonfuls in water  
every four hours. Decrease in twenty-four  
to forty-eight hours to 1 or 2 teaspoonfuls  
and continue at this dose until recovery.

**SEACO**

**THE S. E. MASSENGILL COMPANY**  
Manufacturing Pharmacists  
BRISTOL, TENN.-VA.

Please do not copy or reproduce this picture in any way.

# Food, Drug and Cosmetic Act of 1938

- Drugs or cosmetics must be tested for toxicity before marketing.
- Adequate directions for use needed to be on package
- Some drugs are designated “by prescription only”

# Cranberry crisis of 1959

- Concerns about safety of pesticides used on Cranberries



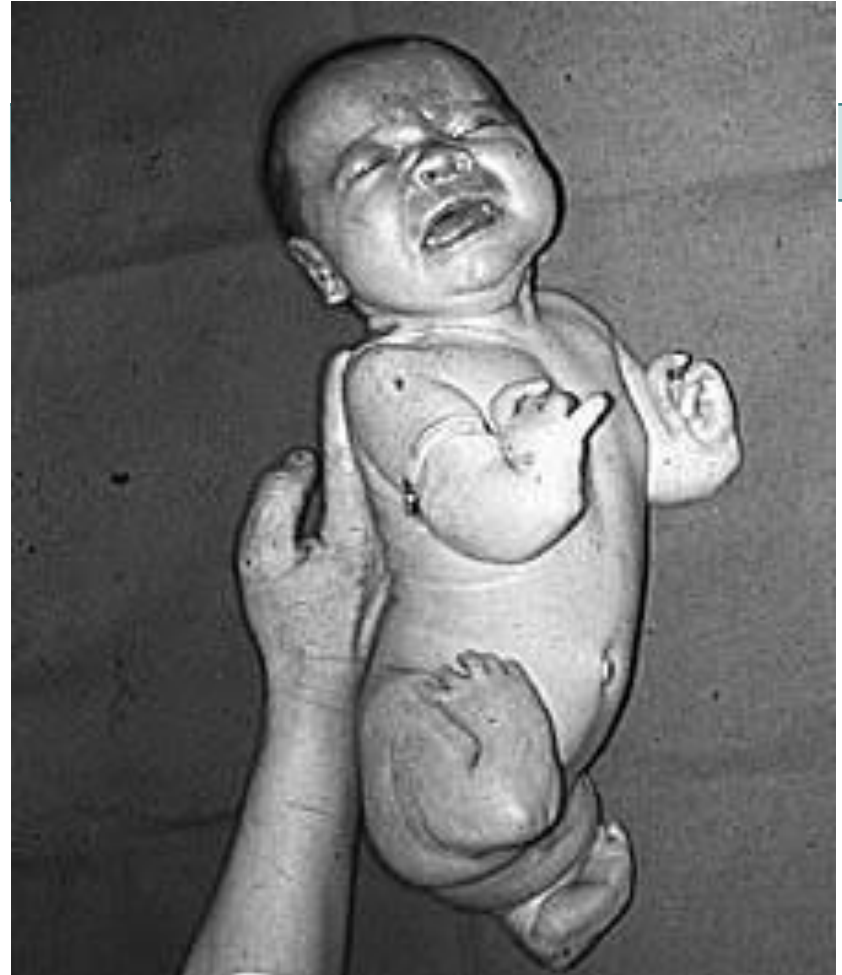


# Thalidomide

**1960-1961**

83 children were born with unusual birth defects, not linked to thalidomide use.

a German scientist makes connections between thalidomide use and thousands of babies born with birth defects.



# Kefauver-Harris Amendments to FDA

**Frances Kelsey, FDA**



FDA can  
demand  
scientific data  
to determine  
the drug works

Congress passes Animal Welfare  
Act,

A series of horizontal lines in teal and light blue colors, with varying lengths and thicknesses, extending from the left edge of the slide towards the right.

1966

# Life magazine 1966




Why do we have federal regulations  
for human experimentation?

A series of horizontal lines in teal and light blue colors, with varying lengths and thicknesses, extending from the left edge of the slide towards the right, positioned below the main text.



In response to scandals, tragedies  
Congress passes the National Research  
Act

1974



Both the history of human  
experimentation and history of  
controversy over human  
experimentation much older

# United States Congress, 1900

considers Senate bill 3424, a law that

would require investigators to disclose in advance the purpose and procedures of any non-therapeutic experiment involving human beings.

# Senate bill 3424

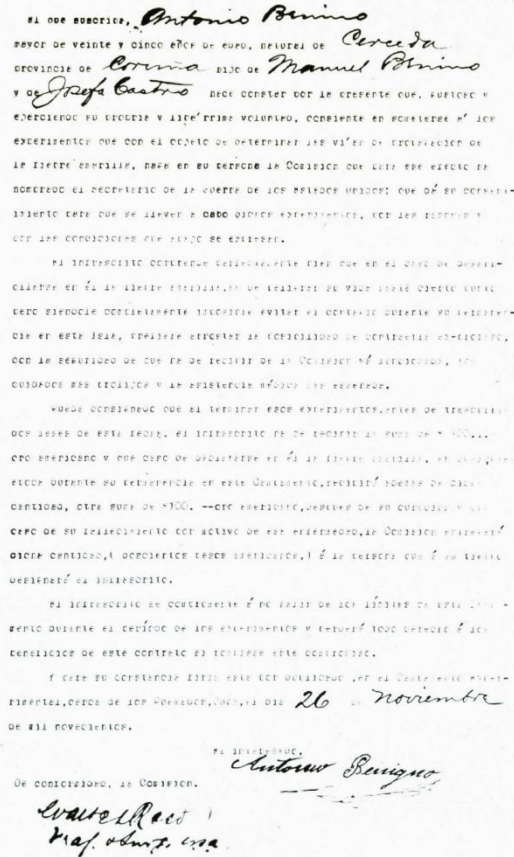
calls for explicit ban on experiments using those persons deemed unable to consent, including infants, children under the age of twenty-one, and pregnant women.

# The Yellow Fever Board in Cuba, 1900





available in both  
English and Spanish



# The undersigned understands...

perfectly well that in case of the development of yellow fever in him, that he endangers his life to a certain extent but it being entirely impossible for him to avoid the infection during his stay in this island, he prefers to take the chance of contracting it intentionally in the belief that he will receive from the said Commission the greatest care and the most skillful medical service.

Subjects receive payment of \$100 in  
American gold  
\$200 goes to family members if death  
occurs in the course of the study



“A written consent was obtained from each one, so that our moral responsibility was to a certain extent lessened. Of course, only the healthiest specimens were experimented upon . . .”

Aristides Agramonte

# Medical research in US

continuing social support for American researchers

celebrating the heroes and martyrs of medical research

self-experimentation and volunteers



3/25/52

NYT

TI

## Contaminated Blood Injection Kills Youth In Seattle Preservation Research Project

SEATTLE, March 24 (AP)—An 18-year-old college honor student died yesterday of an injection of bacterially contaminated blood given during an experiment connected with war research on blood preservation by the University of Washington.

James Stanley Leedom, a freshman at Seattle University, was one of forty volunteers who participated in the project seeking better ways to preserve whole blood.

He died three days after the injection despite every effort to save his life.

Dr. Robert H. Williams, head of the University of Washington Department of Medicine, said the blood had become contaminated "by some phenomenon" after it had been refrigerated.

"The only way we can explain it," said Dr. Williams, "is that the bacteria was able to grow in some manner while the blood was at freezing temperature and not at body temperature."

Both Dr. Williams and Dr. Clement A. Finch, Associate Professor of Medicine in charge of hematology at the university, said they would "gladly participate in the same experiment tomorrow."

They said the bacteria had not yet been identified, but they believed it to be a saprophyte (any organism living on dead or decaying organic matter) that does not grow at body temperature but



Associated Press Wirephoto

James Stanley Leedom

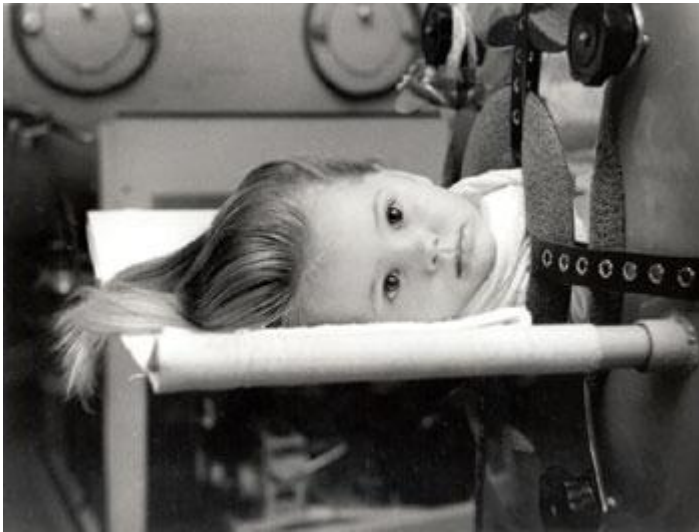
thrives when chilled. It produces shock and high fever.

The father, Stanley P. Leedom, said he held no one at fault for his son's death.

"I don't blame anyone for this," he said. "I just don't want this tragedy to deter in any way from the blood donor program or these experiments."

The boy had planned to major in medicine.

# Polio Epidemics



# Polio epidemic c. 1952







## PARENTAL REQUEST FOR PARTICIPATION OF CHILD IN POLIOMYELITIS VACCINATION FIELD TRIAL

The National Foundation for Infantile Paralysis, Inc., in cooperation with state and local health, medical and educational authorities, is conducting a nation-wide field study of the effectiveness of a vaccine which may be protective against paralysis due to poliomyelitis. The vaccine consists of chemically killed poliomyelitis virus of all three known types. For purposes of this study, several thousand children will be given three injections of this vaccine into the arm over a period of several weeks; at least an equal number of unvaccinated children will be observed so that a comparison can be made between the two groups. The children in each group, those who are vaccinated and those who are not, are equally important to the study. In certain instances it will be necessary to test small samples of blood at intervals during the study to determine the amount of antibodies against poliomyelitis that are present.

I HEREBY REQUEST that my child, \_\_\_\_\_, be vaccinated  
(first name) (middle name) (last name)  
if selected, or otherwise be permitted to participate in the procedures described above without cost to me.

Date \_\_\_\_\_

Signed \_\_\_\_\_

Relationship to Child \_\_\_\_\_  
(Must be parent or legal guardian)

School \_\_\_\_\_

\_\_\_\_\_  
(Street Address or Rural Location)

Grade \_\_\_\_\_

\_\_\_\_\_  
(City, Town or Township)

\_\_\_\_\_  
(State)



# HENRY K. BEECHER, M.D.



Professor of Anesthesia  
Research at Harvard  
Medical School

Convener of the  
Harvard Ad Hoc Brain  
Death Committee

# “Ethics and Clinical Research”

*New England Journal of  
Medicine*  
1966

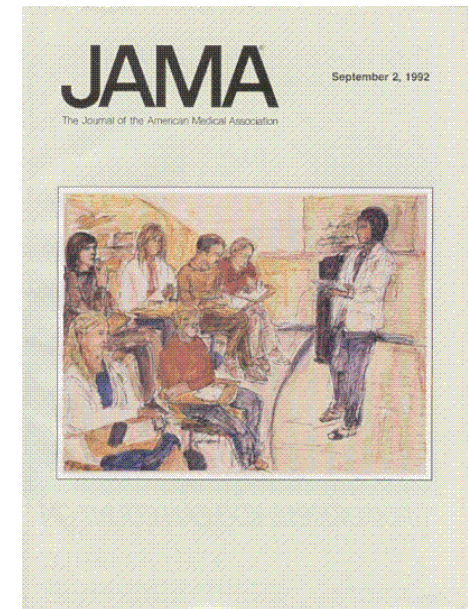
A series of horizontal lines in teal and light blue colors, with varying lengths and thicknesses, extending from the left edge of the slide towards the right.

# 22 examples of “questionable” research practices

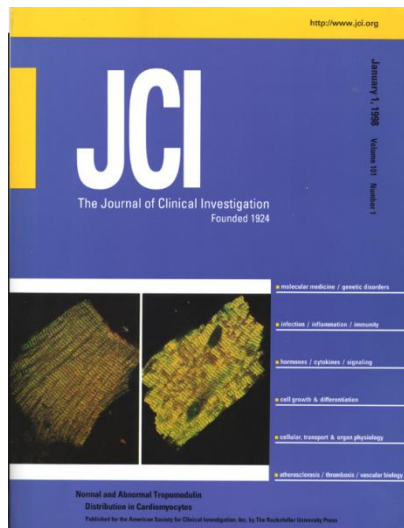
Not from fringe BUT from  
mainstream researchers  
and institutions



5



2



5



2

Prevention of Infective Endocarditis. Guidelines From the American Heart Association. A Guideline From the American Heart Association Rheumatic Fever, Endocarditis, and Kawasaki Disease Committee, Council on Cardiovascular Disease in the Young, and the Council on Clinical Cardiology, Council on Cardiovascular Surgery and Anesthesia, and the Quality of Care and Outcomes Research Interdisciplinary Working Group.

Walter Wilson, Kathleen A. Taubert, Michael Ferencik, Peter H. Lockhart, Larry M. Baddam, Matthew Levine, Ann Bolger, Christopher H. Cabell, Monte Jalasola, Robert S. Baltimore, Jane S. Newburger, Brian J. Simon, Lloyd V. Tani, Michael Garber, Robert O. Bonow, Thomas Pallasch, Stanford T. Shalita, Anne H. Bowdoy, Jane C. Thorne, Patricia Carroll, Timothy Gardner, David Goff, David F. Durack and The Council on Scientific Affairs of the American Dental Association has approved the guideline as a reference to dentistry. In addition, the guideline has been endorsed by the American Academy of Pediatrics, Infectious Disease Society of America, the IS.

Circulation 1997;114:1756-1759, originally published online April 15, 1997.  
DOI: 10.1161/CIRCULATIONAHA.106.183095

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Cover picture: Localization of tropomyosin (green) and  $\alpha$ -actinin (red) in cardiomyocytes isolated from a nontransgenic control (left) and tropomyosin overexpressing transgenic (TGT) mouse (right). Control cells show little or no overlap (yellow) between tropomyosin and  $\alpha$ -actinin labels in control cells, but the abundant yellow signal in TGT cells indicates abundant colocalization of tropomyosin with  $\alpha$ -actinin. See the article by Housman et al., pp. 51-61.

# Publication of the 22 examples

the rest from

*Science, Cancer, J. of  
Urology, Surgery, Gynecology  
and Obstetrics, American J. of  
Medicine, Anesthesiology, and  
American J. Med. Sciences*

# Why HENRY K. BEECHER?



Christian faith?

anesthesia?

experience with  
human subjects  
research?



# Beecher's World War II

- Study of the Severely Wounded
- Work on the placebo effect

# Nazi Experiments



## 1946-47, prosecution of 23 Nazi medical personnel



# United States v. Karl Brandt et al



# Permissible Medical Experiments

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The Nuremberg Code